510(k) Summary

In accordance with 21CFR807.92, the following summary of information is provided;

Date Nov 16th 2012

Submitter: ALPINION MEDICAL SYSTEMS Co., Ltd.

Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd),

Guro-gu, Seoul, Republic of Korea 152-848,

Primary Contact Person Donghwan Kim

QARA Manager

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Guro-gu, Seoul, Republic of Korea 152-848,

Phone: +82 70 7465 2068 Fax: +82 2 851 5590

Email: donghwan.kim@alpinion.com

Secondary Contact Yuchi Chu

Person Address: Suite 229, 10604 NE 38th Place, Kirkland, WA 98033,

United States Phone: 425 949 4907

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Email: ychu@alpinionus.com

Device Trade Name: E-CUBE 15

Common/Usual Name: Ultrasonic Pulsed Doppler Imaging System

Classification Names System, Imaging, Pulsed Doppler Ultrasonic

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-

IYN

Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO

Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX

Predicate Device(s) K120060 E-CUBE 9 Diagnostic Ultrasound System

Device Description:

E-CUBE 15 product is an ultrasound imaging system for medical diagnosis. The system platform provides optimal patient diagnosis workflow with the 18.5" wide flat panel display, ergonomic control panel with easy user interface, optimal image quality.

Indications For Use:

The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); **Pediatric**, Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult & **pediatric**); Peripheral Vascular (PV); and Urology (including prostate).

Technology:

E-CUBE 15 employs the same fundamental scientific technology as its predicate device.

<u>Determination of</u> <u>Substantial Equivalence:</u>

Summary of Non-Clinical Tests:

E-CUBE 15 has been evaluated for biocompatibility, acoustic output as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. E-CUBE 15 and its application comply with voluntary standards as detailed in this premarket submission. The following quality management system measures were applied to the development of E-CUBE 15:

- NEMA UD2, UD3
- AIUM Medical Ultrasound Safety
- IEC60601-1
- + IEC60601-1-1
- IEC60601-1-2
- IEC60601-2-37
- ISO 10993-1

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, E-CUBE 15, did not require clinical studies to support substantial equivalence.

Conclusion:

Alpinion Medical Systems Co., Ltd. considers E-CUBE 15 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

ALPINION MEDICAL SYSTEMS Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA or the requirements will be published in guidance documents.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-002

February 1, 2013

Alpinion Medical Systems, Co., Ltd. c/o Mr. Donghwan Kim QARA Manager 1,6 and 7FL, Verti Tower, 72, Digital-ro(St) 26-gil (Rd) Guro-gu Seoul, 152-848 KOREA REPUBLIC

Re: K123610

Trade/Device Name: E-CUBE 15 Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: November 21, 2012 Received: November 21, 2012

Dear Mr. Kim

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the E-CUBE 15, as described in your premarket notification:

Transducer Model Number

<u>SC1-6H</u>	,	<u>SVC1-6</u>
L3-12H		<u>L3-12X</u>
SP1-5X		<u>L3-8</u>
L8-17X	•	<u>SP3-8</u>
SC1-4H		<u>CW 2.0</u>
E3-10H		<u>CW 5.0</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Sean MABoyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known):

Indications for Use

Device Name: E-CUBE 15
Indications for Use:
The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric, Small Organ (breast, testes, thyroid); Trans-rectal, Trans-vaginal, Musculo-skeletal(Conventional); Musculo-skeletal (Superficial); Cardiac (adult& pediatric); Peripheral Vascular (PV); and Urology (includir prostate).
Prescription Use AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD) (Division Sign Off) Olivision of Radiological Health Office of In Vitro Diagnostics and Radiological Health 510(k) 423610

E-CUBE 15 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)	
Ophthalmic	-									
Fetal	Р	Р	Р		Р	Р	P	Р	, N	
Abdominal	Р	Р	P		P	P	P	Р	N	
Intra-operative (Specify)			-							
Intra-operative (Neuro)			•							
Laparoscopic	1		•					·	ļ <u>. </u>	
Pediatric	N	N	N		N	N	N	N	N	
Small Organ (breast, testes, thyroid)	P	Р	Р		, P	. P	Р	Р		
Neonatal Cephalic	†						-		<u> </u>	
Adult Cephalic	 		`							
Trans-rectal	P	Р	Р		Р	Р	. P	Р		
Trans-vaginal	P	Р	Р		Р	P	Р	P	ļ.,	
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skeletal (Conventional)	Р	Р	Р		Р	, P	Р	Р		
Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р	Р	Р		
Intravascular		-		1						
Cardiac Adult	P	Р	Р	Р	P	Р	P	Р		
Cardiac Pediatric	N	N	N	N	N	N	N	N		
Intravascular (Cardiac)									<u> </u>	
Trans-esoph. (Cardiac)	1									
Intra-cardiac									1	
Peripheral vessel	P	Ρ.	Р		Р	P	P	Р	<u> </u>	
Urology (including prostate)	Р	Р	Р	Τ.	Р	Р	Р	Р		

N = new indication; P = previously cleared by FDA K121888; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diaghostic Devices (OIVD)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

Prescription User (Per 21 CFR 801.109)

51000 K123610

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with SC1-6H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	Mode of Operation									
	В	M	PŴĐ	CWD	Color Doppler	Power Doppler	Tissue Harmonic	Combined* (Specify)	Other** (Specify		
•	İ			<u>-</u>			Imaging	-			
Ophthalmic								·	<u> </u>		
Fetal	P	Р	P		Р	P	Р	Р			
Abdominal	P	Р	Р		Р	Р	P	Р			
Intra-operative (Specify)											
Intra-operative (Neuro)						<u> </u>	<u> </u>		<u> </u>		
Laparoscopic	 										
Pediatric	N	N	N		N	N	N	N			
Small Organ											
(breast, testes, thyroid)					_						
Neonatal Cephalic				T							
Adult Cephalic .	—										
Trans-rectal											
Trans-vaginal	1							<u> </u>			
Trans-urethral	1										
Trans-esoph. (non-Card.)	1	1									
Musculo-skeletal	1	1		1 .							
(Conventional)	'						·				
Musculo-skeletal									1		
(Superficial)		.				<u></u>	<u></u>				
Intravascular				1			<u> </u>				
Cardiac Adult		1	<u> </u>								
Cardiac Pediatric											
Intravascular (Cardiac)		1	1								
Trans-esoph. (Cardiac)				1				,			
Intra-cardiac	+	1	1								
Peripheral vessel		†	† - -						<u> </u>		
Urology (including prostate)	P	Р	Р	 	P	Р	Р	P			

N = new indication; P = previously cleared by FDA K121888; E = added under appendix

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(Division Sign Off)

Division of Radiological Health

Prescription User (Per 21 CFR 801.109)

Office of In Vitro Diagnostics and Radiological Health

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with L3-12H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operation	1 				-	
•	В	М	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify
Ophthalmic	+								
Fetal				1					
Abdominal	 								
Intra-operative (Specify)	· · · · · · ·								
Intra-operative (Neuro)	 								
Laparoscopic	1		-						
Pediatric	1						ļ - -		
Small Organ	P	Р	P		P	Р		Р	
(breast, testes, thyroid)	-	ר	. •		•	•			
Neonatal Cephalic	1								
Adult Cephalic	1								
Trans-rectal									
Trans-vaginal									
Trans-urethral	1								
Trans-esoph. (non-Card.)	1								
Musculo-skeletal (Conventional)	Р	Р	Р		P	Р		Р	
Musculo-skeletal (Superficial)	Р	Р	Р		Р	Р		P	
Intravascular									
Cardiac Adult	"								
Cardiac Pediatric									
Intravascular (Cardiac)		Ì							
Trans-esoph. (Cardiac)	1								
Intra-cardiac									
Peripheral vessel	Р	P	Р		Р	P		Р	<u></u>
Urology (including prostate)				 					

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

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Division of Radiological Health

Prescription User (Per 21 CFR 801.109)

Office of In Vitro Diagnostics and Radiological Health

51000 K123610

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with SP1-5X Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	ie of	Operation	1		-			
	В	М	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic			-					l.	
Fetal								<u> </u>	
Abdominal	P	Р	P		Р	Р	Р	P	
Intra-operative (Specify)			-						
Intra-operative (Neuro)									
Laparoscopic							,		
Pediatric	N	N	N		N	N	N	N	
Small Organ	<u> </u>								
(breast, testes, thyroid)					-				
Neonatal Cephalic	†								
Adult Cephalic	I^-								
Trans-rectal									
Trans-vaginal	<u> </u>		<u>-</u>			-			
Trans-urethral	1		-						
Trans-esoph. (non-Card.)	 								
Musculo-skeletal	1		<u> </u>						
(Conventional)									
Musculo-skeletal	1-		<u> </u>	 					-
(Superficial)						,			
Intravascular	_								
Cardiac Adult	Р	Р	P	P	Р	P	Р	Р	
Cardiac Pediatric				1.					
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac			-						
Peripheral vessel	_		 						
Urology (including prostate)	<u> </u>	1				-			

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Division of Radiological Health

Prescription User (Per 21 CFR 801.109)

Office of In Vitro Diagnostics and Radiological Health

ALPINION MEDICAL SYSTEMS Co., LEGORY K123610

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with L8-17X Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic			· · · ·		·		- <u>-</u>		
Fetal	 				-				
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic		-	_				<u> </u>		
Pediatric		-	,						
Small Organ	Р	Р	P		P	Р	-	Р	
(breast, testes, thyroid)	ļ								
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal				<u> </u>					
Trans-vaginal									
Trans-urethral							<u></u>		_
Trans-esoph. (non-Card.)	T .								
Musculo-skeletal (Conventional)	Р	Р	Р		Р	Р		P	
Musculo-skeletal (Superficial)	Р	Р	Р	-	Р	Р		Р	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac		1							
Peripheral vessel	Р	Р	Р		Р	P		Р	
Urology (including prostate)	\top			†	<u> </u>		-	<u> </u>	

N = new indication; P = previously cleared by FDA K121888; E = added under appendix

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with SC1-4H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)		
Ophthalmic											
Fetal	Р	Р	P		Р	Р	Р	Р			
Abdominal	Р	Р	Р		Р	Р	Р	P			
Intra-operative (Specify)											
Intra-operative (Neuro)				Ī		<u> </u>					
Laparoscopic									·		
Pediatric	N	N	N		N	N	N	N			
Small Organ	1										
(breast, testes, thyroid)						<u> </u>					
Neonatal Cephalic							<u> </u>	, <u></u>			
Adult Cephalic											
Trans-rectal											
Trans-vaginal				Ţ							
Trans-urethral			-					<u>.</u>			
Trans-esoph. (non-Card.)	-								· ·		
Musculo-skeletal				-							
(Conventional)			-								
Musculo-skeletal			Ţ								
(Superficial)				<u> </u>							
Intravascular		1									
Cardiac Adult									ļ		
Cardiac Pediatric								<u> </u>	ļ		
Intravascular (Cardiac)					1		<u> </u>				
Trans-esoph. (Cardiac)				<u> </u>			ļ <u> </u>		<u> </u>		
Intra-cardiac								<u> </u>	ļ		
Peripheral vessel					,	<u> </u>			- -		
Urology (including prostate)	Р	Р	P		Р	P	Р	Р			

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with E3-10H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	В	M	PWD	CWD	Color Doppler	. Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic	 								
Fetal				-					
Abdominal									
Intra-operative (Specify)	1								
Intra-operative (Neuro)									
Laparoscopic			·						<u>. </u>
Pediatric	1			<u> </u>					
Small Organ	1								
(breast, testes, thyroid)				-					
Neonatal Cephalic									<u> </u>
Adult Cephalic	 			<u> </u>					
Trans-rectal	P	Р	Р	1	Р	Р	Р	Р	
Trans-vaginal	Р	Р	Р		P	Р	Р	Р	
Trans-urethral	 								
Trans-esoph. (non-Card.)	<u> </u>			<u> </u>		•			
Musculo-skeletal		1							
(Conventional)									<u></u>
Musculo-skeletal	1.								
(Superficial)									
Intravascular									
Cardiac Adult									<u> </u>
Cardiac Pediatric								<u> </u>	٠
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)	-	1		· ·					
Intra-cardiac	T -								ļ
Peripheral vessel	T-								
Urology (including prostate)	Р	P	Р	1	P	Р		Р	-

N = new indication; P = previously cleared by FDA K121888; E = added under appendix

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Concurrence of CDRH, Office of In-Vitro Diagnostic Devices (OIVD)

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Division of Radiological Health

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with SVC1-6 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	de of	Operation	1					<u> </u>
·	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthamic									
Fetal	Р	Р	P		Р	Р	P	P	Р
Abdominal	Р	P	Р		Р	Р	Р	Р	P
Intra-operative (Specify)			_		-				
Intra-operative (Neuro)	<u> </u>						·		
Laparoscopic					-				<u></u>
Pediatric	P	Р	Р		P	P	Р	P	Р
Small Organ									
(breast, testes, thyroid)		ŀ				ļ			
Neonatal Cephalic									
Adult Cephalic	_	†—							
Trans-rectal	+-						·		
Trans-vaginal	1			1					
Trans-urethral	_			Ì					
Trans-esoph. (non-Card.)				<u> </u>				,	
Musculo-skeletal									
(Conventional)			1	1					
Musculo-skeletal		1							
(Superficial)						· .			
Intravascular	1	_							
Cardiac Adult		1		<u> </u>			i i		
Cardiac Pediatric	+-								
Intravascular (Cardiac)		-		1-					
Trans-esoph. (Cardiac)	-								
Intra-cardiac	-								
Peripheral vessel									
Urology (including prostate)	·P	P	Р		Р	Р	P	P	

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 L3-12X with Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mo	de of	Operation	1					
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal .									
Intra-operative (Specify)	1		•						
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	Ν.		N	N	N	N	
Small Organ (breast, testes, thyroid)	N	N	N		N .	N	, N	N	
Neonatal Cephalic									
Adult Cephalic	 		<u>.</u>						
Trans-rectal			•						
Trans-vaginal			-						
Trans-urethral	1	-		-					
Trans-esoph. (non-Card.)	1								
Musculo-skeletal (Conventional)	N	Ņ	N		N	N	N	N	
Musculo-skeletal	N	N	N		N	N	N	N	
(Superficial)						ı.			
Intravascular			•						
Cardiac Adult						· -			
Cardiac Pediatric									
Intravascular (Cardiac)									•
Trans-esoph. (Cardiac)	<u> </u>								
Intra-cardiac	 					,	-		
Peripheral vessel	N	N	N		N	N	N	N	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA; E = added under appendix

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Prescription User (Per 21 CFR 801.109)	/ Division of Radiological Health
·	Office of In Vitro Diagnostics and Radiological Health

ALPINION MEDICAL SYSTEMS Co., Ltd. 610(n) K123610

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 L3-8 with Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	В	M	PWD	CWD	Color	Power	Tissue	Combined*	Other**
					Doppler	Doppler	Harmonic Imaging	(Specify)	(Specify)
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)					-				
Intra-operative (Neuro)	 	-							
Laparoscopic									
Pediatric	Р	Р	P	<u> </u>	Р	Р		Ρ	
Small Organ	Р	Р	Р	··	Р	Р		Р	
(breast, testes, thyroid)					, 1				
Neonatal Cephalic	1.								
Adult Cephalic		_							
Trans-rectal	-		-					,	
Trans-vaginal	1				,				Ī
Trans-urethral	١.			,		_			
Trans-esoph. (non-Card.)									
Musculo-skeletal	P	P	Р		Р	Р		Р	
(Conventional)					1				
Musculo-skeletal	Р	Р	Р		Р	Р		Р	
(Superficial)					ļ.				
Intravascular	1								
Cardiac Adult	<u> </u>		·	1	 				
Cardiac Pediatric	†								
Intravascular (Cardiac)				<u> </u>					
Trans-esoph. (Cardiac)					-				-
Intra-cardiac									
Peripheral vessel	P	Р	Р		Р	Р		P	
Urology (including prostate)						d under en			

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

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Division of Radiological Health

ALPINION MEDICAL SYSTEMS Co., Ltd. Office of In Vitro Diagnostics and Radiological Health

E-11

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with SP3-8 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	de of	Operation	1			·		
	В	М	PWD	CWD	Color	Power	Tissue	Combined*	Other**
					Doppler	Doppler	Harmonic Imaging	(Specify)	(Specify)
Ophthalmic	-				-				
Fetal				•					
Abdominal	P	Р	P		P	P.	Р	Р	
Intra-operative (Specify)									
Intra-operative (Neuro)	<u> </u>								
Laparoscopic					-				
Pediatric	P	Р	Р		P	Р	P .	Р	
Small Organ	 								
(breast, testes, thyroid)						Ì		. •	
Neonatal Cephalic					_				
Adult Cephalic			· · · · · ·						
Trans-rectal				<u> </u>					
Trans-vaginal	 -								
Trans-urethral	1	-							
Trans-esoph. (non-Card.)	†					7			
Musculo-skeletal	1.		<u>. </u>	1					
(Conventional)		ľ							
Musculo-skeletal	+			1	-				
(Superficial)						1			
Intravascular		1							
Cardiac Adult			<u> </u>						
Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Р	Р	
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)			-						
Intra-cardiac									
Peripheral vessel		1							
Urology (including prostate)							,		

N = new indication; P = previously cleared by FDA K120060; E = added under appendix

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Division of Radiological Health

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ALPINION MEDICAL SYSTEMS Co., Ltd. K123610

^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with CW 2.0 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
. •	В	М	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal	1		-						
Abdominal		<u> </u>							<u></u>
Intra-operative (Specify)	-				-				
Intra-operative (Neuro)					.,				
Laparoscopic	1								
Pediatric									
Small Organ	1.	-				,			
(breast, testes, thyroid)			-						
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal	-								
Trans-vaginal									
Trans-urethral	1								
Trans-esoph. (non-Card.)	1								
Musculo-skeletal			-						
(Conventional)					·-				_
Musculo-skeletal	1								
(Superficial)			İ						<u> </u>
Intravascular									
Cardiac Adult				N					
Cardiac Pediatric				N .					
Intravascular (Cardiac)									
Trans-esoph (Cardiac)				-					
Intra-cardiac	1					1			
Peripheral vessel					1				
Urology (including prostate)					ded under a				

N = new indication; P = previously cleared by FDA; E = added under appendix

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

E-CUBE 15 with CW 5.0 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	В	M	PWD	CWD	Color Doppler	Power Doppler	Tissue Harmonic Imaging	Combined* (Specify)	Other** (Specify)
Ophthalmic									
Fetal									
Abdominal					.,				·
Intra-operative (Specify)				-					
Intra-operative (Neuro)			.4						
Laparoscopic	_								
Pediatric								. · <u> </u>	
Small Organ									
(breast, testes, thyroid)		•							
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal					-			"	
Trans-urethral	-								
Trans-esoph. (non-Card.)									
Musculo-skeletal									
(Conventional)						<u></u>			<u></u>
Musculo-skeletal									
(Superficial)						<u> </u>		_	<u> </u>
Intravascular									
Cardiac Adult			-	N					
Cardiac Pediatric	1		_	N					
Intravascular (Cardiac)	<u> </u>	T	_						
Trans-esoph. (Cardiac)									
Intra-cardiac	† ·								
Peripheral vessel		1					<u></u>		
Urology (including prostate)	1								

N = new indication; P = previously cleared by FDA; E = added under appendix

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^{*} Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D